REMARKS

Applicant has inserted priority information for the present application as required by 37 C.F.R. § 1.78. None of these amendments add new matter to the instant application.

Restriction Requirement

The Examiner has restricted the pending claims into Groups I and II:

Group I: corresponding to claims 1-13, drawn to a method of administering a drug for which the major clearance mechanism in humans is CYP2D6-mediated oxidative biotransformation, classified in class 514, subclasses 280 and 305; and

Group II: corresponding to claims 14-22, drawn to pharmaceutical compositions, classified in class 514, subclass 280 and 305.

Applicant hereby elects to prosecute Group I in this application with traverse.

Applicant traverses the Restriction Requirement imposed by the Examiner. The Examiner states that the invention of Groups I and II are "unrelated to each other" and "have different functions." The Examiner asserts that the search for all inventions would place an undue burden on the Office in view of the diversity in the field of search for each

Pursuant to MPEP § 806.05(h), a product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product, or (B) the product as claimed can be used in a materially different process. The burden is on the examiner to provide an example, but the example need not be documented. If the applicant either proves or provides a convincing argument that the alternative use suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative use or withdraw the requirement.

In Group I, independent claim 1 recites a "*method of administering a drug* for which the major clearance mechanism in humans is CYP2D6 mediated oxidative transformation . . . *in combination with a CYP2D6 inhibitor* . . ." In Group II, independent claim 14 recites s "pharmaceutical composition comprising . . . (a) *a therapeutically effective amount of a drug* for which the major clearance mechanism in

humans is CYP2D6 mediated oxidative transformation . . . (b) *an amount of a CYP2D6 inhibitor* . . . and (c) a pharmaceutically acceptable carrier" These two groups are clearly related by the product and process of using paradigm of MPEP § 806.05(h), i.e., Group I relates to a method of using a certain combination and Group II relates to the pharmaceutical composition embodying said combination.

Contrary to the Examiner's assertion, both inventions have the same function. The invention of the instant application (both groups) has as its object to improve a drug's pharmacokinetic profile by eliminating the effects of the CYP2D6 enzyme which is present in differing amounts in various subsets of the human population. To eliminate dosing problems for those with this high amounts of CYP2D6 in their physiological profile, the invention serves to change extensive CYP2D6-mediated drug metabolizers to poor metabolizers via the co-administration of a CYP2D6 inhibitor, such that all subjects using this invention would have similar pharmacokinetic profiles. The method and the pharmaceutical composition embody this combination of elements and hence serve the same function.

The Examiner has not made any showing as required by MPEP § 806.05(h) that the Groups relate to distinct inventions. That is the Examiner has not shown that either or both (A) the process of Group I as claimed can be practiced with another materially different product, or (B) the product of Group II as claimed can be used in a materially different process. Unless the Examiner can make and adequate showing, this restriction must be withdrawn.

Applicants have not canceled claims directed to Group II subject matter pending Examiner's reconsideration of the restriction under 35 U.S.C. § 121. With the election of Group I, Applicants elect as the species within said Group I:

(2S,3S)-2-phenyl-3-(2-methoxy-5-trifluoromethyoxyphenyl)methylamino-piperidine (as the drug for which the major clearance mechanism in humans is CYP2D6 mediated oxidative transformation)

and quinidine (as the CYP2D6 inhibitor).

No amendment of inventorship is necessary with the election of Group I claims in this application.

In view of the foregoing, Applicants respectfully request favorable reconsideration of the restriction requirement and allowance of the application.

Respectfully submitted,

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